

**REMARKS**

Favorable reconsideration is respectfully requested in view of the following remarks.

**I. CLAIM STATUS**

Claims 2-16 are pending in this application.

Claims 2-5 and 14-16 were examined on the merits and stand rejected.

Claims 6-13 were withdrawn as non-elected subject matter.

**II. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION**

Claims 2-5 and 14-16 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-17 of copending application Serial No. 10/384,606 (the '606 application). See pages 2-3 of the Office Action.

This rejection is respectfully traversed.

An obviousness-type double patenting rejection is applicable when the claims of one application are not patentably distinct from the claims in a commonly owned patent application. See M.P.E.P. § 804, II, B(1). The analysis employed in an obviousness-type double patenting rejection parallels the analysis of a 35 U.S.C. § 103 obviousness determination. Ibid.

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. See M.P.E.P. § 2143.03. Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. See M.P.E.P. § 2143.01. Third, the prior art must provide a reasonable expectation of success. See M.P.E.P. § 2143.02.

Accordingly, to have a judicially created doctrine of obviousness-type double patenting rejection, the claims of one application must be obvious variants of the claims in a copending application.

It is respectfully submitted that the claims of the instant application are not obvious variants of the claims in the '606 application.

The instant claims call for a dry measuring test device for detecting a substance in a liquid sample by measuring the degree of reaction between the substance to be measured and a chromogenic reagent in units of reflectance of light, wherein the test device comprises a single reagent layer comprising (i) a reagent containing a chromogen, (ii) polymer beads containing embedded light reflective particles, and (iii) a matrix comprising a hydrophilic high molecular substance, wherein the matrix contains the reagent and the polymer beads and the content of the polymer beads is 5 to 30 wt% of the total weight of the single reagent layer.

On page 2 of the Office Action of February 2, 2005, the Examiner stated that "although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device using a reagent, polymer bead and reflective particles on the beads."

However, the instant claims require polymer beads containing embedded light reflective particles. It is respectfully submitted that this limitation is neither disclosed nor suggested in the claims of the '606 application. In fact, the claims of the '606 application are silent as to the use of polymer beads containing embedded light reflective particles. As a result, the claims of the instant application are not an obvious variant of the claims in the '606 application. For this reason, the rejection should be reversed.

Furthermore, notwithstanding that the claimed invention is not obvious over the '606 application, the test device disclosed and claimed by the Applicants is believed to be patentable in view of unexpected advantages over the claims of the '606 application. As discussed in the response filed on December 10, 2002, the use of the polymer beads containing embedded light reflective particles exhibits unexpected advantages which are indicative of the non-obviousness of the claimed invention.

When the light reflective particles are directly contained in the reagent layer, there is the following problem in practical use as described on page 2, line 25 to page 4, line 1 of the present specification. Conventionally, in this kind of dry measuring test device for determining a substance to be measured in a liquid sample through the coloring reaction between the substance to be measured and the reagent, in order to enhance measurement accuracy, an attempt was made

to have the light reflective particles directly contained in the reagent layer and have the reagent for coloring contained therein as well. However, if a large amount of light reflective particles is directly contained in the reagent to improve the measurement accuracy, the reagent layer becomes so dense that a liquid sample can hardly penetrate and develop, and as a result, it takes a long time until the amount of the coloring matter generated by the reaction with the reagent becomes sufficiently measurable. Thus, this is a problem in practical use. Further, it is disadvantageous in that the measurement accuracy may possibly be lowered due to dryness if the measuring time is prolonged as described above.

This problem is solved, according to the present invention, by allowing the light reflective particles to be embedded in polymer beads. The advantages of embedding light reflective particles in polymer beads are clearly evidenced by Example 1 and Comparative Example 1 (see pages 19-22) in the present specification, and are not believed to be disclosed or suggested by the claims of the '606 application. The results from these examples demonstrate that for the test device of the present invention (Example 1) the sample liquid permeated the reagent layer well and the reaction rate between the reagent and the substance to be measured was higher than that of conventional dry measuring test device (Comparative Example 1). See page 22, lines 1-13.

Since the claims of the '606 application do not recite or suggest such a limitation, the claims of the '606 application fail to disclose or suggest this unexpected advantage of having the light reflective particles embedded in polymer beads. Accordingly, the use of the polymer beads containing embedded light reflective particles and its advantages are not suggested by the cited application. Thus, claims 2-5 and 14-16 of the present application are believed to be patentably distinct from claims 1-17 of the '606 application.

In view of the above, the provisional rejection of claims 2-5 and 14-16 under the judicially created doctrine of obviousness-type double patenting over claims 1-17 of the copending '606 application is untenable and should be withdrawn.

### **III. OBVIOUSNESS REJECTION**

Claims 2-5 and 14-16 were rejected under 35 U.S.C. § 103(a) as obvious over Fukuoka et al. (2003/0166295), Fukuoka et al. (2003/0175985), Fukuoka et al. (2003/180183) or Fukuoka et al. (U.S. 6,777,243). See page 3 of the Office Action of February 2, 2005.

This rejection is respectfully traversed.

The test for obviousness is set forth above.

Also, as discussed above, the test device of the present invention requires polymer beads containing embedded light reflective particles.

On page 3 of the Office Action of February 2, 2005, the Examiner stated that: "Fukuoka et al. (203/0166295), Fukuoka et al. (2003/0175985), Fukuoka et al. (2003/180183) and Fukuoka et al. (USP 6,777,243) all teach the polymer beads and titanium dioxide in paragraphs [0254], [0256], [0254] and column 37 lines 40+."

However, the cited applications merely list polymer beads and titanium dioxide as examples of granular substances which may constitute the support of the device disclosed by the cited applications. It is respectfully submitted that this is not a suggestion to use polymer beads containing embedded light reflective particles. Furthermore, as discussed above, the use of the polymer beads containing embedded light reflective particles exhibits unexpected results.

No where do the cited applications and patent disclose or suggest polymer beads containing embedded light reflective particles. The use of the polymer beads containing embedded light reflective particles and its advantages are not suggested by any of the cited applications. For these reasons, the rejection should be withdrawn.

Furthermore, it is respectfully submitted that the rejection should be withdrawn, because Fukuoka (2003/0166295), Fukuoka (2003/0175985), Fukuoka (2003/180183) and Fukuoka (USP 6,777,243) are not prior art references against the instant application.

On page 3 of the Office Action, it is indicated that Fukuoka (2003/0166295), Fukuoka (2003/0175985), and Fukuoka (2003/180183) and Fukuoka (USP 6,777,243) qualify as prior art, because they go back to a 371 National Stage filing date of October 30, 1996, whereas the instant

application has a later filing date of October 31, 1996. However, it is respectfully submitted that this characterization is inaccurate.

M.P.E.P. § 1896, II, C states:

(C) If the international application has an international filing date prior to November 29, 2000, apply the reference under the provisions of 35 U.S.C. 102 and 374, prior to the AIPA amendments:

(1) For U.S. patents, apply the reference under 35 U.S.C. 102(e) as of the earlier of the date of completion of the requirements of 35 U.S.C. 371(c)(1), (2) and (4) or the filing date of the later-filed U.S. application that claimed the benefit of the international application;

(2) For U.S. application publications and WIPO publications directly resulting from international applications under PCT Article 21(2), never apply these references under 35 U.S.C. 102(e). These references may be applied as of their publication dates under 35 U.S.C. 102(a) or (b);

(3) For U.S. application publications of applications that claim the benefit under 35 U.S.C. 120 or 365(c) of an international application filed prior to November 29, 2000, apply the reference under 35 U.S.C. 102(e) as of the actual filing date of the later-filed U.S. application that claimed the benefit of the international application.

In this case, the international application for the cited references was filed on October 30, 1996, which is well before November 29, 2000. Accordingly, the references should be applied under the provisions of 35 U.S.C. 102 and 374 prior to the AIPA amendments. Under these circumstances, the cited references are not prior art to the instant application.

Fukuoka (USP 6,777,243) is a divisional of application Serial No. 09/068,050, filed on April 29, 1998, which is the 371 National Stage application of PCT/JP96/03188, filed October 30, 1996. According to M.P.E.P. § 1896, II, C(1), Fukuoka (USP 6,777,243) has a 102(e) date of April 29, 1998, which is the 371 National Stage filing date. This date is after the October 28, 1997 U.S. filing date of the present application.

Fukuoka (2003/0166295), Fukuoka (2003/0175985) and Fukuoka (2003/180183) are U.S. application publications that claim the benefit of the international application under 35 U.S.C. §§ 120 and 365(c). According to M.P.E.P. § 1896, II, C(3), these publications have a 102(e) date of

the actual filing date of the later-filed U.S. application that claimed the benefit of the international application, i.e., March 11, 2003. Please see the PTO Examination Guidelines for 35 U.S.C. § 102(e), a copy of which is enclosed, particularly Example 6.

For these reasons, it is respectfully submitted that Fukuoka (2003/0166295), Fukuoka (2003/0175985), Fukuoka (2003/180183) and Fukuoka (USP 6,777,243) are not prior art references against the instant application. Accordingly, the rejection is untenable and should be withdrawn.

Thus, for the reasons set forth above, the rejection of claims 2-5 and 14-16 under 35 U.S.C. § 103(a) as obvious over Fukuoka et al., application Serial No. 2003/0166295, Fukuoka et al., application Serial No. 2003/0175985, Fukuoka et al., application Serial No. 2003/0180183 or Fukuoka et al., U.S. Patent No. 6,777,243 is untenable and should be withdrawn.

### CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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